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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,505	01/09/2006	Joerg Rosenberg	M/43212-US-1	4705

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EXAMINER	
CHO, JENNIFER Y	
ART UNIT	PAPER NUMBER
1621	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/539,505	ROSENBERG ET AL.	
	Examiner	Art Unit	
	Jennifer Y. Cho	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/9/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Acknowledgement is made of Applicant's Response to Election/Restriction filed 1/4/2007.

Upon further review, the restriction has been withdrawn.

Claim Rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 are rejected under 35 U.S.C. 102b as being anticipated by Kothrade et al. (US 6,284,803 B1).

Kothrade et al. teaches a pharmaceutical formulation (column 14, line 45) in dosage form (column 1, line 4) comprising fenofibrate as the active ingredient (column 7, line 39), in the form of a molecular dispersion (column 10, line 48), and a polymeric binder composed of methyl methacrylate, acrylic acid, cellulose acetate phthalate and hydroxypropylmethylcellulose phthalate (column 5, lines 11-13, 20-21) and other conventionally acceptable excipients (column 1, lines 4-7), which include flow regulators and silicates/silica gel (column 6, lines 1 and 12). The formulation is further obtainable by melt extrusion (column 2, line 8; column 5, line 35). The formulation has a ratio of

free carboxyl groups to esterified carboxyl groups around 1:1, based on the weight percentage of methyl methacrylate to acrylic acid (column 2, lines 56-61) and the use of Eudragit types, which Applicant uses to exemplify this ratio preference (column 5, line 12; column 10, line 39) (see also specification page 7, lines 3-10). The formulation comprises 0.1 to 95%, preferably from 20 to 80%, in particular 30 to 70% by weight of the active substance (column 6, lines 61-63), with ranges of 15-83% for the binder (column 2, lines 19-45), in which the enteric binder (Eudragit types) is in the preferable range of up to 75% by weight of the binder component (column 4, lines 65-67; column 5, line 1 and 12) and with the range of up to 100%, in particular 0.02-50% of pharmaceutically/physiologically acceptable additives (column 5, lines 66-67; column 6, lines 7-8). The preceding percentages would include a formulation in which the content of active substance component relative to binder is from 20 to 30% by weight. Therefore these claims are fully met.

Claim Rejections – 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kothrade et al. (US 6,284,803 B1).

Kothrade et al. teaches a pharmaceutical formulation (column 14, line 45) in dosage form (column 1, line 4) comprising fenofibrate as the active ingredient (column 7, line 39), in the form of a molecular dispersion (column 10, line 48), and a polymeric binder composed of methyl methacrylate, acrylic acid, cellulose acetate phthalate and hydroxypropylmethylcellulose phthalate (column 5, lines 11-13, 20-21) and other conventionally acceptable excipients (column 1, lines 4-7), which include flow regulators and silicates/silica gel (column 6, lines 1 and 12). The formulation is further obtainable by melt extrusion (column 2, line 8; column 5, line 35). The formulation has a ratio of free carboxyl groups to esterified carboxyl groups around 1:1, based on the weight percentage of methyl methacrylate to acrylic acid (column 2, lines 56-61) and the use of Eudragit types, which Applicant uses to exemplify this ratio preference (column 5, line 12; column 10, line 39) (see also specification page 7, lines 3-10). The formulation comprises 0.1 to 95%, preferably from 20 to 80%, in particular 30 to 70% by weight of the active substance (column 6, lines 61-63), with ranges of 15-83% for the binder (column 2, lines 19-45), in which the enteric binder (Eudragit types) is in the preferable range of up to 75% by weight of the binder component (column 4, lines 65-67; column 5, line 1 and 12) and with the range of up to 100%, in particular 0.02-50% of pharmaceutically/physiologically acceptable additives (column 5, lines 66-67; column 6, lines 7-8). The preceding percentages would include a formulation in which the content of active substance component relative to binder is from 20 to 30% by weight.

The reference however, does not exemplify Applicant's particular formulation.

However, the art teaches that all three components of the formulation: fenofibrate, binder component and other excipients/additives, can be combined (column 1, lines 4-7; column 7, lines 10-12 and 39).

In reference to claim 15, which describes a method for oral administration, it is the position of the examiner that since the dosage is in tablet form (column 10, line 67), the expected mode of administration is orally. Additionally, Applicant states that fenofibrate is usually administered orally (specification page 1, line 15).

In reference to claim 1 and 4, which describes the binder as an enteric binder/enteric polymer, because the art describes the polymeric binder with the same components as Applicant's, which include methyl methacrylate, acrylic acid, cellulose acetate phthalate and hydroxypropylmethylcellulose phthalate (column 5, lines 11-13, 20-21), it is the position of the Examiner that the enteric property is inherent to the binder/polymer composition.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to combine these components to make a formulation of fenofibrate for pharmaceutical oral administration. The expected result would be an effective lipid-regulating tablet in dosage form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Y. Cho whose telephone number is (571) 272 6246. The examiner can normally be reached on 9 AM - 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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